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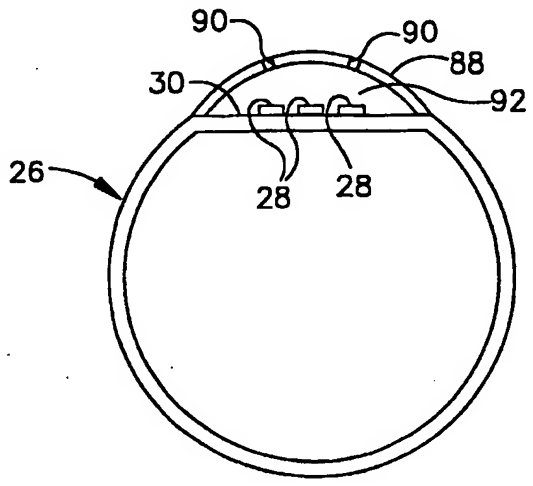
(54) Title: REMOTELY INTERROGATED MEDICAL IMPLANT WITH SENSOR



(57) Abstract: A medical implant device is provided which includes a structure implantable within a body of a living animal for assisting in carrying out a function within the body. The device further includes a transducer element mounted on a carrier for sensing a parameter associated with the structure. Moreover, the device includes a communication circuit coupled to the transducer element for producing an output based on the sensed parameter and which serves to communicate the output non-invasively to a receiver located outside the body. The carrier is bonded to the structure such that portion of the structure located immediately beneath the carrier is isolated from stresses generated in regions of the structure not under the carrier.

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TITLE: REMOTELY INTERROGATED MEDICAL IMPLANT WITH SENSOR

Cross-Reference to Related Application

This application claims priority under 35 USC §119 to United States Provisional Patent Application Serial No. 60/167,102, filed on November 23, 1999.

Technical Field

The present invention relates generally to medical implant devices, and more particularly to devices which may be interrogated remotely from outside the body.

Background of the Invention

Various types of medical implant devices have been developed over the years. In many instances, such devices enable humans to live longer, more comfortable lives. Implant devices such as pacemakers, artificial joints, valves, grafts, stents, etc. provide a patient with the opportunity to lead a normal life even in the face of major heart, reconstructive, or other type surgery, for example.

It has been found, however, that the introduction of such implant devices can sometimes lead to complications. For example, the human body may reject the implant device which can ultimately lead to infection or other types of complications. Alternatively, the implant device may malfunction or become inoperative. Therefore, it is desirable to be able to monitor the condition of the implant device. On the other hand, it is highly undesirable to have to perform invasive surgery in order to evaluate the condition of the device.

Still further, it is desirable to be able to monitor conditions related to the use of implant devices. For example, in heart patients it may be helpful to know the amount of blood flowing through a stent or graft in order to

evaluate the health of the patient. Again, however, it is undesirable to have to perform invasive surgery in order to evaluate such conditions.

Techniques have been developed which enable the function of an implant device to be monitored remotely from outside the body of the patient. These techniques involve including one or more sensors in the device for sensing the condition of the device. The device further includes a small transceiver for processing the output of the sensors and transmitting a signal based on the output. Such signal typically is a radio frequency signal which is received by a receiver from outside the body of the patient. The receiver then processes the signal in order to monitor the function of the device.

Other approaches involve coupling a receiver located outside the body of the patient to the sensors in the device using other types of coupling techniques. For example, the sensors produce an impedance loading effect which varies as a function of the measurand. Such loading effect is sensed non-invasively using inductive coupling. Alternatively, acoustic signals are transmitted through the body to/from the sensors in order to obtain the desired information non-invasively.

Unfortunately, installing one or more sensors with such implant devices can be complex, time intensive, and thus costly. Thus, there is a strong need in the art for an implant device and manner for installing the same which is less complex, less time intensive, and thus less costly.

Summary of the Invention

According to one aspect of the invention, a medical implant device is provided. The device includes a structure implantable within a body of a living animal for assisting in carrying out a function within the body. In addition, the device includes a transducer element mounted on a carrier for sensing a parameter associated with the structure. Moreover, the device includes a communication circuit coupled to the transducer element for

producing an output based on the sensed parameter and which serves to communicate the output non-invasively to a receiver located outside the body. The carrier is bonded to the structure such that portion of the structure located immediately beneath the carrier is isolated from stresses generated in regions of the structure not under the carrier.

In accordance with another aspect of the invention, an implantable annulus sensor is provided which includes a base portion and a transducer element mounted on the base portion for measuring a parameter associated with a function occurring within a body of a living animal. Additionally, the sensor includes at least one flexible strap attached to the base portion and which may be wrapped for securing the base portion to a structure within the body of the living animal.

According to still another aspect of the invention, a medical implant device is provided which includes a structure implantable within a body of a living animal for assisting in carrying out a function within the body. Additionally, the device includes a transducer element mounted on a carrier for sensing a parameter associated with the structure, and a communication circuit coupled to the transducer element for producing an output based on the sensed parameter and serving to communicate the output non-invasively to a receiver located outside the body. Moreover, the device includes a cap for protecting the transducer element from undesired contact with surrounding portions of the body of the living animal.

To the accomplishment of the foregoing and related ends, the invention, then, comprises the features hereinafter fully described and particularly pointed out in the claims. The following description and the annexed drawings set forth in detail certain illustrative embodiments of the invention. These embodiments are indicative, however, of but a few of the various ways in which the principles of the invention may be employed. Other objects, advantages and novel features of the invention will become

apparent from the following detailed description of the invention when considered in conjunction with the drawings.

Brief Description of the Drawings

Fig. 1 is a side view of a graft having a remotely interrogatable annulus sensor and patch sensor in accordance with an exemplary embodiment of the present invention;

Fig. 2 is a cross section of the annulus sensor in accordance with the present invention;

Fig. 3 is partial view of the annulus sensor showing a preferred flat portion with an array of strain gages in accordance with the present invention;

Fig. 4 is a partial view of the annulus sensor of Fig. 1 bonded to the graft using an adhesive in accordance with the present invention;

Fig. 5 is a partial cross section of the annulus sensor of Fig. 1 in an embodiment where the annulus is crimped to the graft in accordance with the present invention;

Fig. 5A is a partial cross section in which the annulus is crimped to the graft according to another embodiment of the present invention.

Fig. 6 is a partial cross section of the annulus sensor of Fig. 1 in an embodiment where the annulus is sewn to the graft in accordance with the present invention;

Fig. 7 is a cross section of the annulus sensor in an embodiment which utilizes shape memory alloy fibers to adhere the annulus to the graft;

Figs. 8A, 8B and 8C are partial cross sections of the annulus sensor of Fig. 7 illustrating the manner in which the shape memory alloy fibers engage the graft;

Fig. 9 is a partial cross section of the annulus sensor in an embodiment using a carrier plate with shape memory alloy fibers to adhere the annulus to the graft;

Fig. 10 is a side view of an annulus sensor designed to self lock around the graft in accordance with the present invention;

Fig. 11 is a side view of another embodiment of an annulus sensor designed to self lock around the graft in accordance with the present invention; and

Fig. 12 is a side cross section of an annulus sensor having a protective cap in accordance with the present invention.

Description of the Preferred Embodiments

The present invention will now be described with reference to the drawings, wherein like reference numerals are used to refer to like elements throughout.

Systems are known to exist for remotely interrogating a medical implant device. Typically, the system includes a medical implant device which is implanted in a living animal such as a human patient. The medical implant device can be any of a wide variety of different types of devices including, for example, a stent, graft or shunt, artificial joint, etc.

Such implant devices typically are configured to carry out or assist in carrying out a function within the patient. For example, in the case of a stent the device prevents the closing of an arterial wall and permits the flow of blood therethrough. In the case of a graft, the device serves to couple blood flow between two separate ends of an artery. The device may instead consist of an artificial hip or knee which facilitates movement of the leg of the patient. Other functions include, but are not limited to, a hemodialysis shunt and spinal brace, for example.

The devices include a sensing circuit which serves to sense a parameter associated with the function performed by the device. For example, in the case of a stent or graft the sensor may be used to detect the degree of restenosis which occurs within the device. Alternatively, for example, the sensing circuit may detect an amount of strain or displacement

which occurs in an artificial hip or knee. Still further, the sensor may serve to sense the condition of the implant device in carrying out its intended function. For example, in the case of a pacemaker the sensor may detect the pulse rate.

Such known systems further include interrogation instrumentation for remotely interrogating the implant device in order to evaluate the device function. The interrogation instrumentation includes, for example, an interrogator unit which is positioned outside the patient in close proximity to the implant device. The interrogator unit serves to activate the sensing circuit within the implant device and receive information from the device. The sensing circuit includes, for example, a small radio frequency transmitter which transmits the information from the sensing circuit. Alternatively, the sensing circuit may be designed to have a variable impedance loading effect on the interrogator unit. In either case, the output of the sensing circuit may vary in relation to the sensed parameter (e.g., blood flow, pressure, amount of restenosis, etc.).

Referring now to Figs. 1 thru 3, the present invention will be described in the context of a medical implant device in the form of a graft or shunt. It will be appreciated, however, that the invention has application in a variety of different types of implant devices such as stents, artificial joints, intramedullary rods, protective plates, etc. Thus, the present invention in its most general sense is not intended to be limited to a particular type of implant device. Nevertheless, it will be appreciated that the present invention is particularly well suited for implants such as grafts, stents, etc.

Figs. 1 thru 3 illustrate an embodiment of the invention in which the implant device is a graft 20 for joining separate ends of a blood vessel (not shown). The graft 20 has a tube shaped structure 22 made up of a thin material such as stainless steel, or a composite and/or plastic material. Using known techniques, the graft 20 is implanted within the patient by securing respective ends of a blood vessel to corresponding ends of the graft

20. Consequently, blood will flow through the interior of the graft 20 as represented by arrow 24.

The graft 20 further includes an annulus 26 which is fitted around the outer circumference of the tube 102. As is shown in Fig. 3, the annulus 26 serves as a carrier for one or more transducer sensing elements 28 (e.g., strain gage elements) which are mounted in or on the outer surface of a flat portion 30 preferably included in the annulus 26. In the case of more than one strain gage element 28, the elements may be distributed about the outer circumference of the annulus 26. In another embodiment, for example, the strain gage elements 28 may be mounted on the inner surface of the annulus 26 or on both the inner and outer surfaces.

The annulus 26 with the strain gage elements 28 is designed to sense changes in pressure within the graft 20. As the diameter of the tube 22 expands or contracts radially, such changes are detected by the strain gage elements 28 on the annulus 26. An output produced by the strain gage elements 28 varies in impedance as a function of the change in pressure, and the output is coupled to a sensing circuit 32 via electrical lines 34. Consequently, a change in pressure within the graft 20 results in a variation in the impedance presented to the sensing circuit 32. It has been shown that a change in pressure exerted by the blood within a graft or shunt is a reliable indicator of vascular problems. Such problems may include clogging within the graft or shunt, for example, or clogging within the vessel.

The sensing circuit 32 is mounted to the structure 22 as shown in Fig. 1, or to the annulus 26 itself. The sensing circuit 32 may be based on any of a variety of known techniques suitable for permitting non-invasive interrogation. For example, the sensing circuit 32 may be configured to be interrogated non-invasively using a variable impedance loading effect. Such a configuration is described in detail in commonly assigned, copending United States patent application Serial No. 09/275,308 to Spillman, et al., entitled *"Remotely Interrogated Diagnostic Implant Device with Electrically*

Passive Sensor", filed March 24, 1999, and in corresponding PCT International Published Application WO0056210 A. The entire disclosure of each of these applications is incorporated herein by reference.

Alternatively, the sensing circuit 32 may be configured to utilize RF telemetry techniques, for example, to transmit a signal to an analyzer outside the body of the patient. The load measured by a strain gage elements 28 in the annulus 26 may serve to change the oscillation frequency of an RF oscillator included in the sensing circuit 32. An antenna (not shown) provided within the sensing circuit 32 serves to transmit the RF signal output by the oscillator to the analyzer which in turn determines the measured load based on the frequency of the received signal. Details on the use of RF telemetry to non-invasively obtain information from medical implants can be found, for example, in United States Patent No. 5,807,258, the entire disclosure of which is incorporated herein by reference. As the particular configuration of the sensing circuit 32 to permit non-invasive interrogation is not critical to the present invention, further details thereof have been omitted for sake of brevity.

In the exemplary embodiment, the graft tube 22 is made of a thin, compliant material which tends to deform measurably as a result of changes in blood pressure within the graft 20. As a particular example, the tube 22 is a conventional graft made of a compliant woven fabric. The annulus 26 preferably is made of a thin, flexible material such as a biocompatible plastic or metal or a paralyene coated material of choice.

The annulus 26 includes the strain gage elements 28 formed on the outer surface of the annulus 26. In the exemplary embodiment, the strain gage elements 28 are piezoresistive devices whose resistance changes as a function of mechanical strain of the annulus in the direction of its circumference. The piezoresistive devices are formed using MEMs technology, patterned lithography, etc., either directly on the annulus 26 material, or are subsequently mounted to the annulus 26 via a suitable

adhesive, etc. The outputs of the strain gage elements 28 are combined as desired in parallel, series, as a Wheatstone bridge, etc., via conductive lines 36 (Fig. 3) formed on the annulus 26, for example. The conductive lines 36 are coupled to lines 34 to produce a resistance which varies as a function of the pressure exerted on the annulus 26 by the tube 22. The sensing circuit 32, in turn, provides a means by which the measured pressure is communicated non-invasively to a receiving apparatus or analyzer outside of the body of the patient.

The material of which the annulus 26 is made is preferably stiffer than the woven fabric or other compliant material making up the tube 22. According to one embodiment, prior to the graft 20 being installed in the patient, the annulus 26 is placed around the circumference of the tube 22 so as to slightly compress the tube 22. As a result, any expansion which occurs in the tube 22 due to blood flowing therethrough will result in an expansion of the annulus 26, and hence a change in the output resistance of the strain gage elements 28. Experience has shown that with a 6 millimeter ID teflon graft, there is approximately a 0.004 inch increase in diameter of the graft 20, for example, when blood is introduced therethrough at a pressure of 100 millimeters of mercury. Thus, by forming the annulus 26 around the circumference of the tube 22 to be slightly compressed, e.g., on the order of 0.004 inch, the annulus 26 will be subjected to the majority of the load due to blood pressure.

In accordance with the present invention, the annulus 26 is mounted to the outer circumference of the tube 22 according to a number of different techniques described below in connection with Figs. 4-11. According to one embodiment, the annulus 26 is mounted to the tube 22 using a friction or interference fit. However, this embodiment is less preferred as it has been found that local motions of the graft 20 are transmitted to the material under the annulus 26 and are detected by the strain gage elements 28.

Thus, a more preferred embodiment is illustrated in Fig. 4. According to the embodiment shown in Fig. 4, an adhesive 40 is provided along the edges 42 and 44 of the annulus 26. The adhesive 40 serves to bond the edges 42 and 44 of the annulus 26 to the tube 22. As a result, the tube material located immediately beneath the flat portion 30 is isolated from stresses generated in regions of the tube 22 not under the annulus 26. The adhesive 40 may be any suitable type of biocompatible adhesive or an adhesive with a biocompatible covering (not shown).

Fig. 5 represents another embodiment for adhering the annulus 26 to the tube 22. In this embodiment, the annulus 26 is mechanically crimped to the tube 22 along the edges 42 and 44. More specifically, the annulus 26 includes a groove 46 about the inner circumference along each of the edges 42 and 44. During manufacture, the annulus 26 is placed about the tube 22. An axially directed compression force is exerted on the tube 22 to cause nubs 50 of the compliant material making up the tube 22 to form in the grooves 46. The sides of the annulus 26 are then compressed towards each other along the edges 42 and 44 so as to crimp the annulus 26 in secure fixed engagement with the nubs 50. Fig. 5A shows an embodiment in which the nubs 50 are more pronounced. Again, as a result, the tube material located immediately beneath the flat portion 30 is isolated from stresses generated in regions of the tube 22 not under the annulus 26.

Referring to Fig. 6, another embodiment for adhering the annulus 26 to the tube 22 is shown. In this embodiment, the annulus 26 includes predrilled holes 52 about its circumference along each of the edges 42 and 44. The edges 42 and 44 are then sutured or sewn to the wall of the tube 22 using filament(s) 54. If necessary, the tube 22 also includes predrilled holes 56, depending upon the material used to form the tube 22 and the ease with which the filament 54 may be inserted through the tube 22. As in the previous two examples, in this embodiment the tube material located

immediately beneath the flat portion 30 is isolated from stresses generated in regions of the tube 22 not under the annulus 26.

The bonding methods of Figs. 4-6 are also advantageous in that they allow for a simplification of the design. Since only the region of the graft 20 directly under the strain gage elements 28 needs to be isolated from the rest of the graft 20, only the flat portion 30 needs to be so bonded around its perimeter. Since the flat portion 30 will be held in place against the graft tube 22 by such bond, the remainder of the annulus 26 may be dispensed with in another embodiment. In such an embodiment, the sensor is reduced to a simple flat patch with the strain gage elements 28 mounted thereto. The shape of the patch can be rectangular similar to the flat portion 30. Alternatively, the shape of the patch may be circular or some other shape, e.g., ovoid.

As an example, Fig. 1 shows a circular-shaped patch type sensor 58. The patch sensor 58 can be made of the same material as the annulus 26. In addition, the patch sensor 58 is adhered to the tube 22 along its perimeter using any of the methods described above, and particularly the adhesive (Fig. 4), crimping (Fig. 5) or suturing (Fig. 6).

Fig. 7 illustrates another embodiment of the annulus 26. In this embodiment, shape memory alloy (SMA) fibers are used to adhere the perimeter of the flat portion 30 to the tube 22. The perimeter of the flat portion 30 includes straight SMA fibers 60 which extend generally radially inwardly as shown in Fig. 7. During installation of the annulus 26 on the graft tube 22, the annulus 26 is slipped over a flaccid tube 22 and positioned at the desired location as represented in Fig. 8A. With the aid of an auxiliary bladder (not shown) inserted in the graft tube 22, an application of air or water pressure presses the fibers 60 into the wall of the tube 22 as shown in Fig. 8B.

The fibers 60 are designed to penetrate the wall of the tube 22 at least partially as the tube 22 is pressed into engagement. In the case of a

woven body tube 22 or thin compliant material, the fibers 60 will penetrate the wall without the need for preformed holes in the tube 22. In the event preformed holes are necessary, such holes can be provided prior to engagement with the fibers 60.

Next, the fibers 60, which either partially or completely penetrate the will of the tube 22 are subjected to a thermally induced phase change. The SMA fibers 60 are designed using conventional techniques such that with the thermally induced phase change, the fibers 60 transform to a curled shape designed to fixedly hook the flat portion 30 to the tube 22 as shown in Fig. 8C. Again, the tube material located immediately beneath the flat portion 30 is thus isolated from stresses generated in regions of the tube 22 not under the annulus 26.

Fig. 9 illustrates a variation of the embodiment shown in Figs. 7 and 8A-8C. In such variation, the fibers 60 are initially arrayed on a separate, thin, foil carrier 64 instead of being arrayed on the perimeter of the annulus flat portion 30 as in the embodiment of Figs. 7 and 8A-8C. The carrier 64 is placed inside the graft tube 22 at the desired position with the fibers 60 facing the wall of the tube 22. Mechanical or hydraulic pressure applied to the carrier forces the fibers 60 to protrude through the wall. The protruding fibers 60 are configured so as to slip into a set of matching holes preformed in the annulus 26. As in the previous embodiment, a thermally induced phase change is then introduced which causes the fibers 60 to hook and bind the assembly together.

In the embodiment of Fig. 9, the carrier 64 would stay in the graft tube 22. Alternatively, the SMA fibers 60 could be designed to retract from the foil carrier 64 and hook into the wall of the tube 22 as part of the phase change. This would allow the carrier 64 to be removed.

The bonding techniques of Figs. 4-9 can be applied to either an annulus sensor or patch type sensor as will be appreciated. In addition, it will be appreciated that rather than bonding the annulus/sensor unit (e.g.,

strain gage elements) directly to the tube 22, a mounting unit may instead be bonded to the tube 22 using the same techniques. The mounting unit (not shown) is designed to receive the sensor which is configured to be fixedly mounted to the mounting unit (e.g., via a snap-fit into a frame). The present invention contemplates such variations.

Figs. 10 and 11 relate to annulus sensors which provide for fast yet secure attachment to the graft tube 22 or a native blood vessel, for example, using a self-locking technique. Figs. 10 and 11 each show an annulus in which a curved loop of the annulus is a self-locking two piece strap that closes around a vein, artery or shunt, for example. Attachment is performed, for example, while the blood vessel is under hydrostatic pressure.

In the embodiment of Fig. 10, the annulus 26' includes a flat portion 30 on which the strain gages 28 are located. Strap pieces 70 and 72 are flexible plastic or metal plates with some bending stiffness, with means of gripping the enclosed blood vessel, etc., and itself. The inherent bending stiffness of the strap pieces 70 and 72 assures a secure closed state as they are forced to slide over and grip one another by interlocking teeth 74. The strap pieces 70 and 72 are of thinner stock than the base having the flat portion 30 to provide flexibility. To provide the boundary fixity around the flat portion 30, additional sharp, small pins or SMA pins 76 are located along the edge of the flat portion 30 that serve to grip the vessel wall. The hinges 78 shown in Fig. 10 can be as simple as transition points between thicker and thinner parts of the annulus 26', although they could also be true pinned hinges. The entire annulus 26' can be manufactured by injection molding using nylon, for example. The annulus 26' could be made with only a single hinge point 78 in another embodiment, about which all rotation occurs upon closure.

Fig. 11 illustrates another embodiment similar to the embodiment of Fig. 10. However, one strap piece 70 has a series of teeth 80, and the other strap piece 74 has a toothed slot or ring 82 into which the strap piece

70 is inserted. Similar to the straps used to bind a collection of wires, the strap piece 70 may be pulled to close the annulus 26" around a vessel and is secured by the toothed slot or ring 82. In an alternate embodiment, the strap piece 70 does not require teeth as the toothed slot or ring 82 has sufficient bite to directly engage the strap piece 70. The strap pieces 70 and 74 may be, but are not required to be, essentially without bending stiffness. Again, the annulus may be formed using injection molding, for example.

In each of the embodiments of Figs. 10 and 11, the annulus is installed when the graft or native vessel is under hydrostatic pressure, i.e., is not flaccid. The open annulus is placed around the pressurized graft or blood vessel and is closed and tightened while observing the output of the strain gage elements 28. Tightening is stopped when the output of the strain gage elements 28 reaches a non-zero constant value, i.e., further incremental tightening produces insignificant changes in readout.

Fig. 12 illustrates another feature of the invention whereby a protective cap 88 is introduced to protect the transducer element (e.g., strain gage 28) on the flat portion 30. It may be desirable to prevent unwanted contact of the outer surface of the transducer element 28 by muscle, skin or other body tissue. Any normal (i.e., perpendicular) force transmitted to this surface can alter the deflection of the transducer element causing an error in the pressure measurement.

Accordingly, the cap 88 is provided in accordance with the invention. The cap 88 is made of metal or plastic, for example, and is placed over the transducer element(s) 28 and is fixedly secured around the perimeter of the flat portion 30 as shown in Fig. 12, for example. The cap 88 prevents unwanted contact of the outer surface of the transducer element by the surrounding muscle, skin, etc. The cap 88 preferably includes one or more small holes, slots, etc. (generally designated as 90). Alternatively, the cap 88 is formed of a mesh material with multiple holes, slots, etc. The holes or

slots 90 serve to avoid creating a captive air volume in region 92 between the outer surface of the transducer elements 28 and the cap 88. Such a captive air volume can prevent free deflection of the flat portion 30 as will be appreciated. In addition, the holes or slots 90 create a means for liquid blood or other fluid to reach the outside of the transducer elements 28 in the case where fluidic pressure surrounding the annulus 26 is of interest.

Although the cap 88 is shown herein only in the context of the annulus sensor, it will be appreciated that the cap 88 may be employed with a patch type sensor without departing from the scope of the invention.

Although the exemplary embodiments involve a strain gage element 28 having a resistance which changes as a function of the amount of strain, another embodiment can incorporate a strain gage which produces a capacitance or inductance that changes as a function of strain as will be appreciated. Furthermore, other different types of transducer sensor elements using cantilever beams, MEMs technology, etc. may be used. The present invention is not intended to be limited to any particular type of sensor element in its broadest sense.

For example, the transducer sensing element 28 can be any of a variety of known types of sensors which may be used to sense a functional parameter within the living body. Such parameters may include, but are not limited to, vascular parameters such as blood flow rate, blood pressure, oxygen content, cholesterol, restenosis, glucose level, temperature, etc.; hemotology parameters such as blood gases, blood chemistry, hemoglobin content, etc., and skeletal/muscular parameters such as force, strain, displacement, etc. As mentioned above, the element 28 itself may be characterized as an impedance based sensor whose resistance, capacitance and/or inductance varies directly with respect to frequency as a function of the sensed parameter, or another type sensor whose output can be converted into a variable impedance. Exemplary sensor types include electrical, piezoelectric, sonic optical, microfluidic, chemical, membrane,

thermal, magnetohydrodynamic, an NMR varient, magnetic, magnetostrictive, biological, microelectromechanical sensors (MEMs), etc.

In the particular examples discussed herein, the sensing element 28 may be a MEMs device whose impedance varies as a function of the amount or rate of blood flow through a stent or graft. Alternatively, the sensing element 28 may be a surface acoustic wave (SAW) device which can detect blood flow. In yet another alternative, the sensing element 28 may be a piezoelectric device within a stent or graft for detecting blood pressure.

Although the invention has been shown and described with respect to certain preferred embodiments, it is obvious that equivalents and modifications will occur to others skilled in the art upon the reading and understanding of the specification. For example, various other types of implant devices can benefit from the present invention and the invention is not intended to be limited only to shunts and grafts in its broadest application. The present invention includes all such equivalents and modifications, and is limited only by the scope of the following claims.

What is claimed is:

1. A medical implant device, comprising:

a structure implantable within a body of a living animal for assisting in carrying out a function within the body;

a transducer element mounted on a carrier for sensing a parameter associated with the structure; and

a communication circuit coupled to the transducer element for producing an output based on the sensed parameter and serving to communicate the output non-invasively to a receiver located outside the body,

wherein the carrier is bonded to the structure such that portion of the structure located immediately beneath the carrier is isolated from stresses generated in regions of the structure not under the carrier.

2. The medical implant device of claim 1, wherein the carrier is a portion of an annulus designed to fit around the structure.

3. The medical implant device of claim 2, wherein the portion of the annulus is generally flat.

4. The medical implant device of claim 2, wherein the carrier is bonded to the structure with an adhesive.

5. The medical implant device of claim 2, wherein the carrier is bonded to the structure via mechanical crimping.

6. The medical implant device of claim 2, wherein the carrier is bonded to the structure via sewn sutures.

7. The medical implant device of claim 1, wherein the carrier has a shape of a patch placed on a surface of the structure.

8. The medical implant device of claim 7, wherein the carrier is bonded to the structure with an adhesive.

9. The medical implant device of claim 7, wherein the carrier is bonded to the structure via mechanical crimping.

10. The medical implant device of claim 7, wherein the carrier is bonded to the structure via sewn sutures.

11. The medical implant device of claim 1, wherein the carrier represents a mounting element on which the transducer element may be mounted subsequent to the mounting element being secured to the structure.

12. The medical implant device of claim 1, wherein the structure comprises a graft.

13. An implantable annulus sensor, comprising:

a base portion;

a transducer element mounted on the base portion for measuring a parameter associated with a function occurring within a body of a living animal;

at least one flexible strap attached to the base portion and which may be wrapped for securing the base portion to a structure within the body of the living animal.

14. The sensor of claim 13, wherein the sensor includes a flexible strap at each end of the base portion.

15. The sensor of claim 14, wherein each of the flexible straps has teeth which serve to interlock with the teeth on the other flexible strap in order to secure the base portion to the structure.

16. The sensor of claim 14, wherein one of the flexible straps includes a toothed slot or ring for receiving the other flexible strap in order to secure the base portion to the structure.

17. The sensor of claim 13, wherein the base portion includes at least one pin for fixing the sensor to the structure.

18. The sensor of claim 13, wherein the structure comprises at least one of a native blood vessel and a graft.

19. A medical implant device, comprising:

a structure implantable within a body of a living animal for assisting in carrying out a function within the body;

a transducer element mounted on a carrier for sensing a parameter associated with the structure;

a communication circuit coupled to the transducer element for producing an output based on the sensed parameter and serving to communicate the output non-invasively to a receiver located outside the body; and

a cap for protecting the transducer element from undesired contact with surrounding portions of the body of the living animal.

20. The medical implant device of claim 19, wherein the cap comprises at least one opening for permitting fluid flow through the cap.

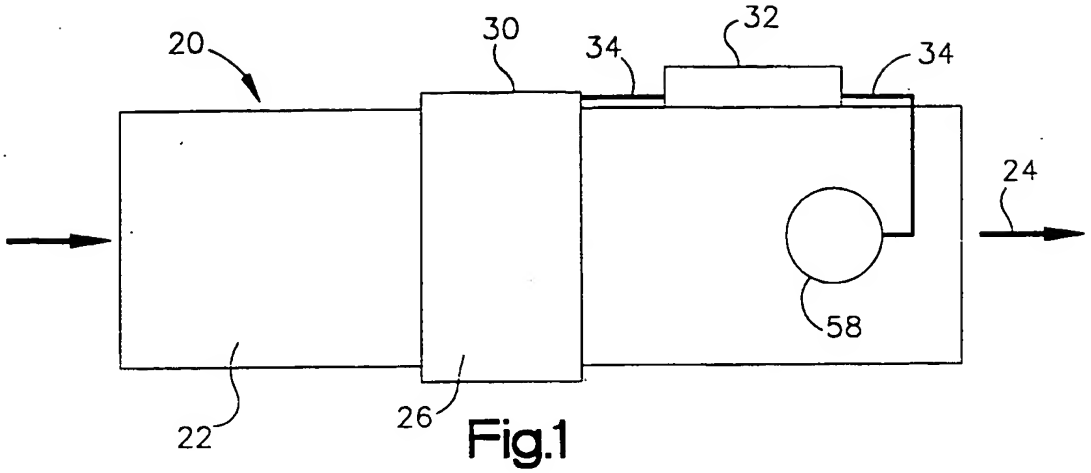

Fig.1

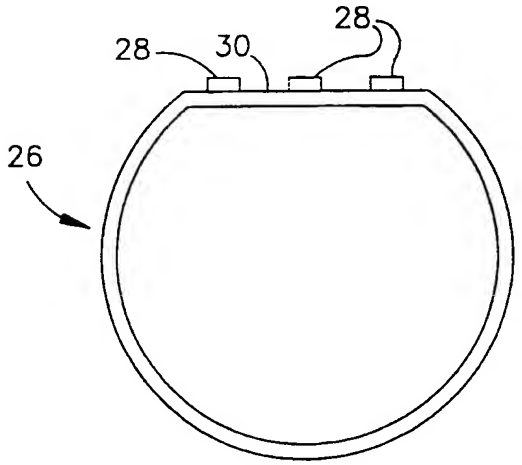

Fig.2

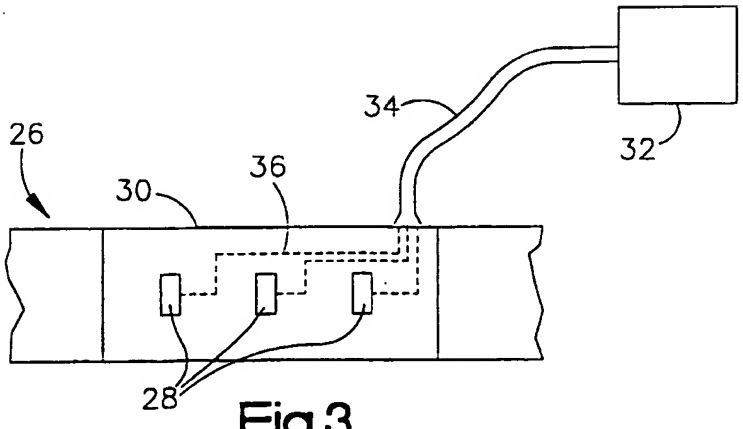

Fig.3

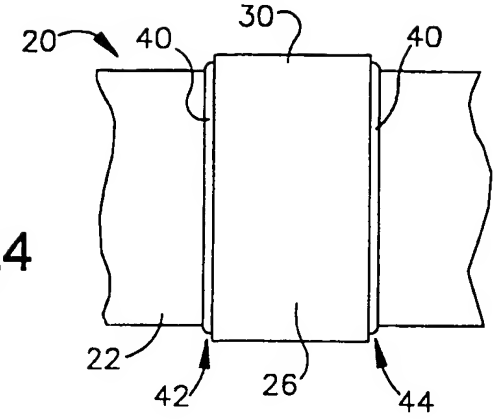

Fig.4

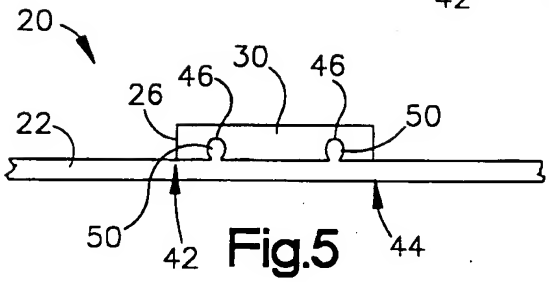

Fig.5

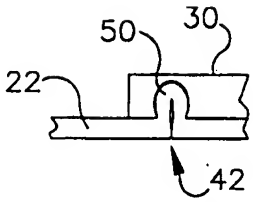

Fig.5A

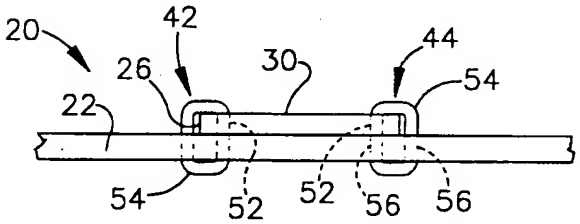

Fig.6

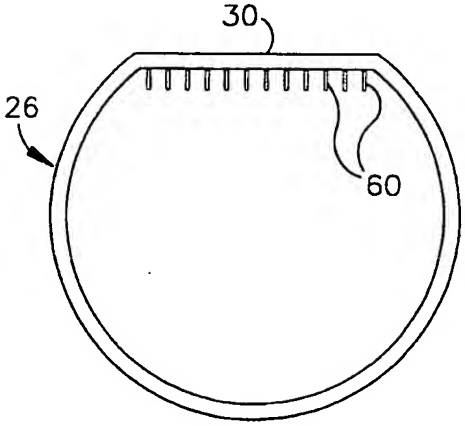

Fig.7

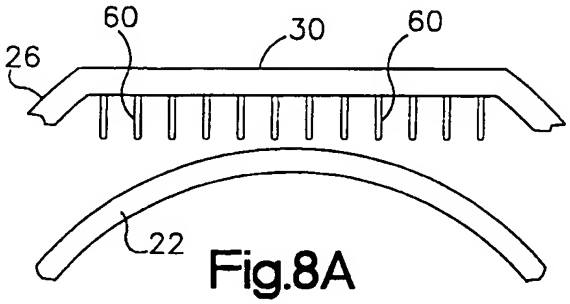

Fig.8A

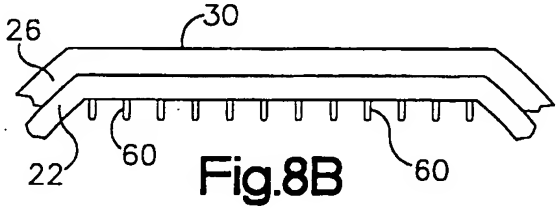

Fig.8B

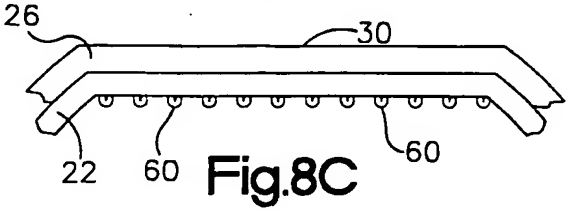

Fig.8C

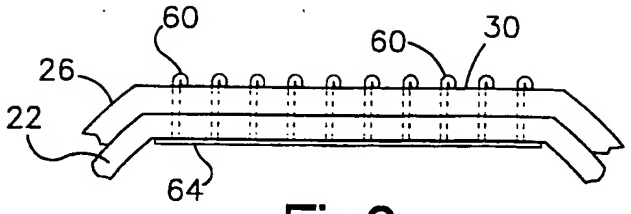

Fig.9

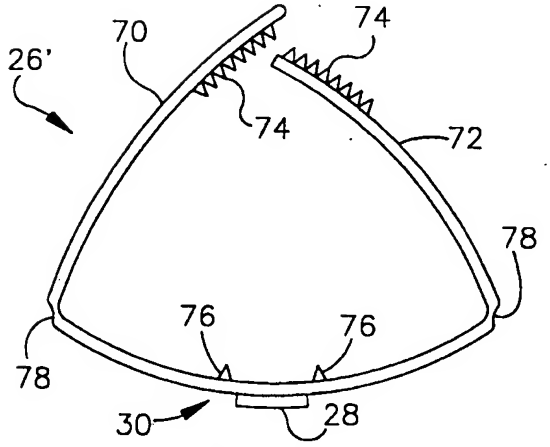

Fig.10

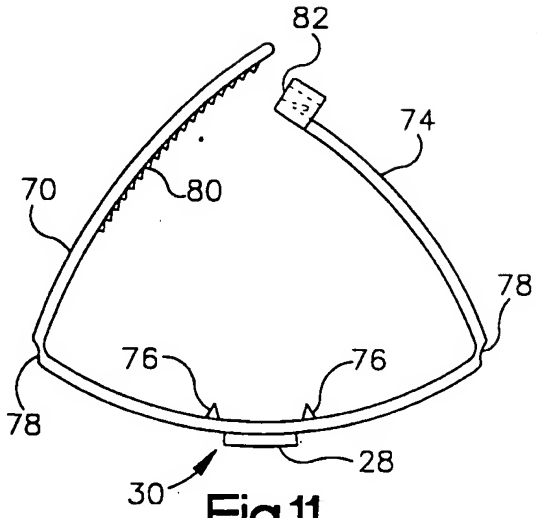

Fig.11

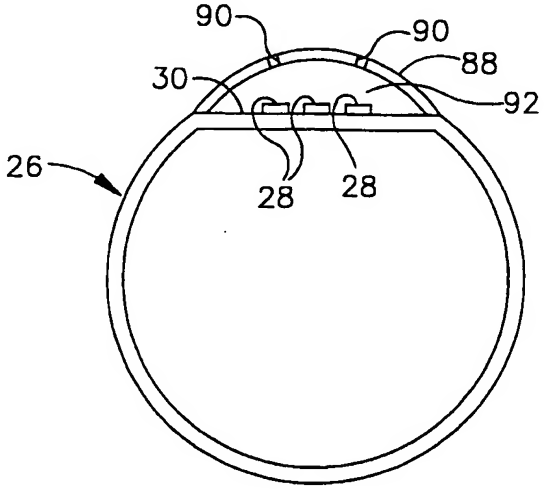

Fig.12

INTERNATIONAL SEARCH REPORT

Internation plication No
PCT/US 00/32196

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 26530 A (CIMOCHOWSKI ET AL.) 3 June 1999 (1999-06-03) page 23, line 1 -page 26, line 18 page 28, line 11 -page 31, line 34 figures 1-19	1,19
Y		13
A		2,4,7,8, 12

Y	WO 89 06513 A (BAYLOR COLLEGE OF MEDICINE) 27 July 1989 (1989-07-27) page 5, line 1 -page 7, line 24 figures 1-3	13
A		1,18,19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 April 2001	02/05/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Chen, A

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PCT/US 00/32196

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 487 760 A (VILLAFANA) 30 January 1996 (1996-01-30) column 3, line 24 -column 4, line 29 column 3, line 36 - line 42 figure 2	1,19
A		2,11,13

X	US 3 661 146 A (COMPAGNIE GENERALE D'ELECTRICITE) 9 May 1972 (1972-05-09) column 2, line 6 - line 46 figure 2	13
A		1-4,11, 14,18,19

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A	US 5 634 462 A (TYLER ET AL.) 3 June 1997 (1997-06-03) column 6, line 10 - line 23 column 7, line 52 -column 8, line 6 column 10, line 30 - line 60 figures 7A-8C	14-16

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